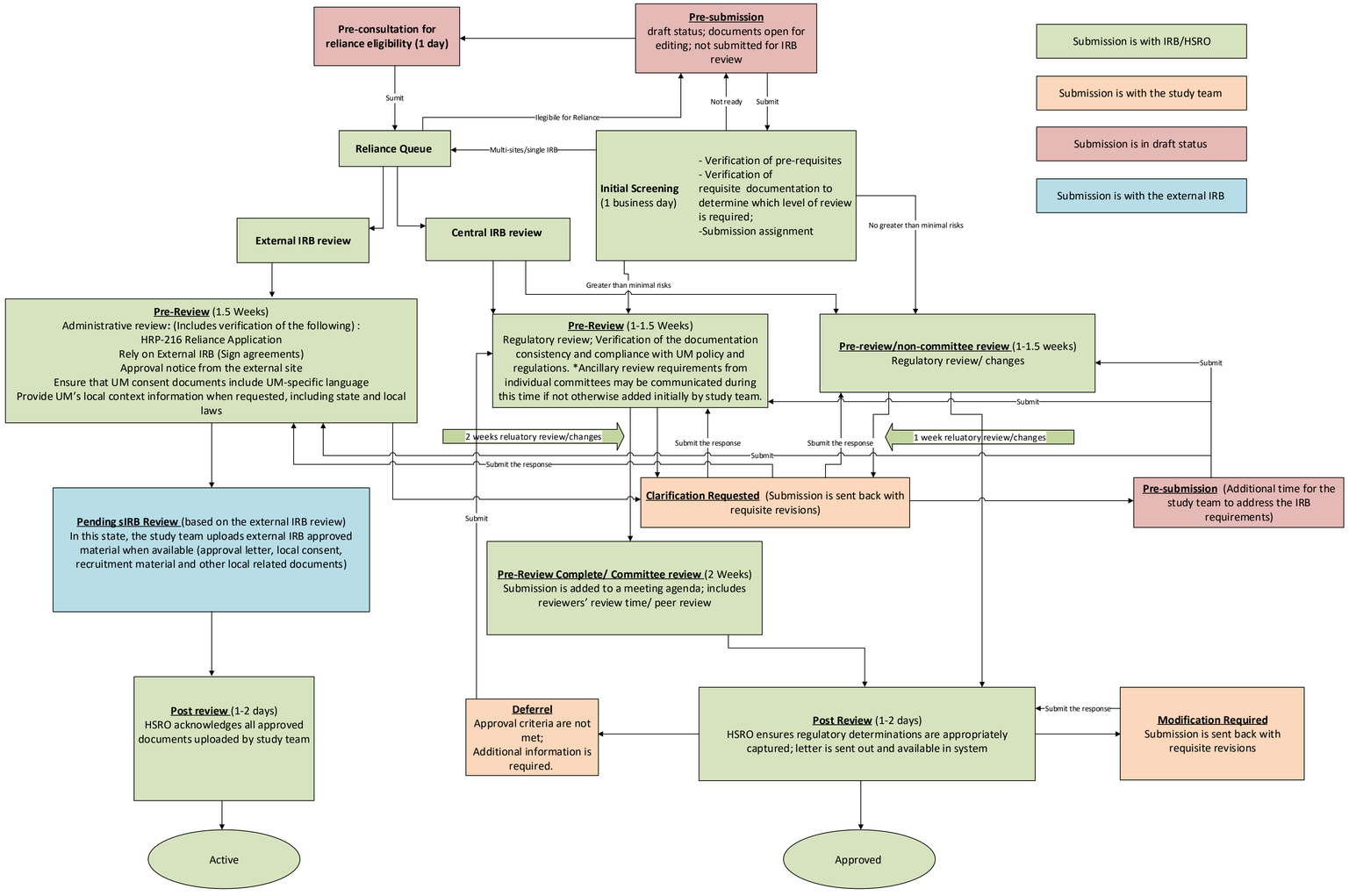
Pre-consultation for reliance eligibility (1 day)
Pre-submission
draft status; documents open for editing; not submitted for IRB review
Submission is with IRB/HSRO
Submission is with the study team
Submission is in draft status
Submission is with the external IRB
Sumit
Ilegibile for Reliance
Not ready
Submit
Reliance Queue
Multi-sites/single IRB
Initial Screening
(1 business day)
- Verification of pre-requisites
- Verification of requisite documentation to determine which level of review is required;
-Submission assignment
No greater than minimal risks
External IRB review
Central IRB review
Greater than minimal risks
Pre-Review (1.5 Weeks)
Administrative review: (Includes verification of the following) :
HRP-216 Reliance Application
Rely on External IRB (Sign agreements)
Approval notice from the external site
Ensure that UM consent documents include UM-specific language
Provide UM's local context information when requested, including state and local laws
Pre-Review (1-1.5 Weeks)
Regulatory review; Verification of the documentation consistency and compliance with UM policy and regulations. *Ancillary review requirements from individual committees may be communicated during this time if not otherwise added initially by study team.
Pre-review/non-committee review (1-1.5 weeks)
Regulatory review/ changes
Submit
2 weeks reluatory review/changes
Submit the response
Submit
Sbumit the response
1 week reluatory review/changes
Submit the response
Clarification Requested (Submission is sent back with requisite revisions)
Pre-submission (Additional time for the study team to address the IRB requirements)
Pending sIRB Review (based on the external IRB review)
In this state, the study team uploads external IRB approved material when available (approval letter, local consent, recruitment material and other local related documents)
Pre-Review Complete/ Committee review (2 Weeks)
Submission is added to a meeting agenda; includes reviewers' review time/ peer review
Post review (1-2 days)
HSRO acknowledges all approved documents uploaded by study team
Deferrel
Approval criteria are not met;
Additional information is required.
Post Review (1-2 days)
HSRO ensures regulatory determinations are appropriately captured; letter is sent out and available in system
Submit the response
Modification Required
Submission is sent back with requisite revisions
Active
Approved